Testimony Before the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Health, Regarding Current Issues Related to Medical Liability Reform

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Presented by Sara Rosenbaum

Good afternoon Mr. Chairman and Members of this Subcommittee. Thank you for the opportunity to testify before the Subcommittee this afternoon on the important topic of medical liability reform.

I am a professor of health law and policy at the George Washington University School of Public Health and Health Services. I have taught, studied, and written about health law for 20 years following the earlier portion of my career spent in the representation of low income individuals and families. I am the co-author of one of the nation's leading health law textbooks. Over a near-30 year time period, I have testified before Congress on a broad array of topics in health law and policy.

I would like to focus my remarks on the key elements of H.R. 5, The Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2003. It is my assumption that this legislation offers a starting point for the development of legislative policy in the 109th Congress.

The stated purpose of H.R. 5 is to "improve patient access to health care services" and "[reduce] the excessive burden" placed on health care by the current liability system. According to CBO estimates for HR 5, the impact on medical malpractice premiums would range from 0% liability premium savings in one-fifth of all states (because of state caps already in place) to significantly higher than the 25%-30% savings norm in about a third of the states. It is important to note in the 2 years since HR 5 passed in the House, more states have moved to place limits on non-economic damages. Data available through the National Conference of State Legislatures (NCSL) indicate that as of 2004, only about a dozen states did not impose any limits. Legislative action by the end of the

year may have reduced this number further. It is unclear in my view whether more than a handful of states would be affected by the recovery caps in HR 5, were it to be re-introduced at this point.

It is also important to note that HR 5 contains no provisions to either incentivize or require efforts to reduce and report on medical errors, despite the fact that the Institute of Medicine has ranked death from preventable medical errors one of the nation's leading causes of death.

In my opinion, the question thus becomes whether provisions such as those found in HR 5 can be justified in view of the bill's negligible-to-none impact on the cost of malpractice premiums, the absence of any impact on the cost of health insurance premiums, and the absence of any provisions aimed at making recoveries swifter and fairer for individuals killed or injured by preventable errors. Comparing the bill's negligible to no impact on cost and quality against heightened burdens that it places on injured persons and their families, I conclude that the answer is no.

Key Elements of H.R. 5

H.R. 5 would establish strict federal standards, including caps on non-economic damages, statutes of limitations, limits on attorney's fees, damages payouts, collateral source rules, and the procedures and standard of proof necessary to support claims of punitive damages related to malicious intent or willful and wanton disregard of patient wellbeing. Taken together, these standards can be expected to not simply curb limits on

non-economic damages, but reduce access to lawyers and the courts because of the procedural constraints and severe limits on recoveries.

The FDA "Shield"

Of particular concern in my view is the shield against recovery of punitive damages (which themselves are severely limited) accorded under the legislation. The Act would prohibit any punitive damages for products that either have received pre-market FDA approval or that are "generally recognized among qualified experts as safe and effective pursuant to conditions established by" the FDA. In other words, the FDA is not required to have weighed in at all for the shield to be triggered; "general recognition" among "qualified experts" (undefined) would suffice to prevent the recovery of even modest punitive damages. Furthermore, the shield would protect not only the manufacturer but also its distributor (§7(c)), as well as the supplier of raw input materials in manufacturing the product. Protection would be total no matter how wanton, willful, and intentional the misconduct. *It appears that the Act would shield even negligible punitive damages, even were the claim to involve intentional product tampering by a distributor of an FDA approved drug.*

The rationale underlying the provisions such as the FDA shield in (§7(c)) – which is irrebuttable and unprecedented in its breadth – has been explicitly rejected by the United States Supreme Court. In *Bragdon v Abbott* 524 U.S. 624 (1998), the Court refused to recognize CDC universal safety precaution guidelines as irrebuttable proof of the existence of a safety standard for professionals treating patients with HIV. The

majority noted in their opinion that treating federal agency action as irrebuttable evidence of what is reasonable is unwarranted, since standards may either be incomplete or rest on an incomplete record and therefore must be independently validated by a court, through the use of objective evidence. Here, the FDA standard in question is the very pre-marketing standard that has been the subject of enormous controversy in recent months, as Vioxx and other drug approval scandals have come to light. The conflicts of interest that have emerged in these scandals undermine any notion in my view that an FDA pre-market review standard would constitute conclusive – or potentially even persuasive – evidence of reasonableness.

Statutes of Limitations

The Act imposes a three-year statute of limitations in all but the narrowest of circumstances. Many states currently use longer statutes of limitations precisely because it can take far longer for the true consequences of medical negligence to manifest themselves. As a result, many states provide for statutes of limitations substantially longer than the typical three year time period granted for ordinary negligence.

The Eclipsing of Federal Civil Rights and Other Rights

The Act contains no rule of construction reconciling its provisions with other federal laws. In essence, any claim, regardless of its underlying theory, arising out of any civil action involving health care and involving a health care provider would be subject to the limitations of the Act.

The term "health care lawsuit" is defined as

> any health care liability claim concerning the provision of health care goods or services or any medical product affecting interstate commerce, or

> any health care liability action concerning the provision of health care goods or services or any medical product affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, or market, promoter or seller of a medical product, regardless of the theory of liability on which the claim is based or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim. Such a term does not include a claim or action which is based on criminal liability; which seeks civil fines or penalties paid to Federal State or local government; or which is grounded in antitrust.* * * §9(7)

A "health care liability action" means

> A civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor supplier, marketer, promoter, or seller of a medical product, *regardless of the theory of liability on which the claim is based*, or the number of plaintiffs, defendants or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim. §9(8)

A "health care liability claim" means

> A demand by any person, whether or not pursuant to ADR against a health care provider, health care organization, or the manufacturer, distributor, supplier, marketer or promoter or seller of a medical product * * * which are based on the provision of, use of, payment for (or the failure to provide, use or pay for) health care services or medical products, *regardless of the theory of liability on which the claim is based* * * * §9(9)

The term "health care goods or services" means

> Any goods or services provided by a health care organization, provider or by any individual working under the supervision of a health care provider that relates to the diagnosis, prevention or treatment of any human disease or impairment or the assessment of the health of human beings. §9(12)

The popular understanding of this legislation, as reflected in press coverage, is that it is intended to shield individual clinical practitioners against punishing liability judgments.

However, the bill's actual reach is breathtaking because the Act contains no limiting language.

The sweep of the above-cited definitions effectively means that any claim against any health care corporation becomes a health care liability claim, thereby permitting a defendant to invoke the bill's numerous protections. The law's protections would appear to be triggered even in cases that do not involve medical injuries in the medical negligence context, simply because the defendant is a health care corporation: claims involving alleged civil rights violations; claims involving alleged acts of fraud and corruption on the part of health care companies, brought by ERISA plans or health care suppliers; and any claim that can be characterized as a "demand" against a "provider."